



Docket No. MCP-294

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Harry S. Sowden

Serial No. : 09/966,497 Art Unit: 1732

Filed : September 28, 2001 Examiner: Angela Y. Ortiz

For : SYSTEMS, METHODS AND APPARATUSES FOR MANUFACTURING  
DOSAGE FORMS

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November 26, 2003  
(Date of Deposit)

David R. Crichton  
(Name of applicant, assignee, or Registered Representative)

David R. Crichton  
(Signature)

November 26, 2003  
(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure Statement mailed on October 6, 2003.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with  the first or  second After Final Submission, therefore:

- Statement in Accordance with §1.97(e)  
(attached); or
- Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- Statement in Accordance with §1.97(e)  
(attached); or
- Please charge Deposit Account No. 10-0750/MCP0294/DRC the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
  - In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
  - Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not

enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a) (2) (i)).

There are no listed references which are not in the English language.

The relevance of those listed references which are not in the English language is as follows:

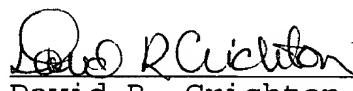
Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

Copies of the references listed on the search report(s) are included except for those previously cited in an IDS mailed

Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP-294/DRC. This form is submitted in triplicate.

Respectfully submitted,

  
\_\_\_\_\_  
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Reg. No. 37,300  
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DATED: November 26, 2003



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		3,146,169		D. Stephenson et al.	08-25-1964	
		4,139,589		Monique Beringer et al.	02-13-1979	
		4,230,693		Henry J. Izzo et al.	12-29-1990	
		4,271,206		Harry F. Fariel et al.	06-02-1981	
		4,273,793		Harry F. Fariel et al.	06-16-1981	
		4,362,757		Andy C. Chen et al.	12-07-1982	
		4,372,942		Paul A. Cimiluca	02-08-1983	
		4,425,332		Michael H. James	01-10-1984	
		4,749,575		Avner Rotman	06-07-1988	
		4,762,719		Mark Forester	08-09-1988	
		4,929,446		Raymond A. Bartolucci	05-29-1990	
		4,980,169		Alfred Oppenheimer et al.	12-25-1990	
		5,002,970		George A. Eby, III	03-26-1991	
		5,075,114		Edward J. Roche	12-24-1991	
		5,213,808		Daniel Ba-Shalom et al.	05-29-1990	
		5,368,863		James B. Eckenhoff et al.	11-29-1994	
		5,391,378		Richard Sanderson	02-21-1995	
		5,405,642		Paul M. V. Gilis et al.	04-11-1995	
		5,489,436		Michael R. Hoy et al.	02-06-1996	
		5,578,336		Woodrow C. Monte	11-26-1996	
		5,614,207		Manoj N. Shah et al.	03-25-1997	
		5,681,584		Louis Savastano et al.	10-28-1997	
		5,853,760		Karsten Cremer	12-29-1998	
		5,871,781		Garry L. Myers et al.	02-16-1999	
		6,103,257		Keith Nisonoff	08-15-2000	
		6,200,590		John G. Eley	03-13-2001	
		6,248,760		Paul C. Wilhelmsen	06-19-2001	
		6,365,185		Wolfgang A. Ritschel	04-02-2002	
		2001/0001280	A1	Liang-Chang Dong et al.	05-17-2001	

Examiner Signature	Date Considered
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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		DE	27 10 307		Verfahren zur Herstellung von Verpackung von festen pharmazeutischen Dosiseinheiten (English abstract attached)	09-15-1977		
		DE	198 34 180	A1	Benckiser N.V. (English abstract attached)	02-03-2000		
		DE	199 54 420	A1	LTS Lohmann Therapie-Systeme AG (English abstract attached)	05-31-2001		
		DE	199 63 569	A1	Reckitt Benckiser N.V. (English abstract attached)	07-26-2001		
		EP	0 294 993	B1	Pfizer Inc.	12-14-1991		
		EP	0 387 885	B1	Bristol-Myers Squibb Company	09-19-1990		
		EP	0 481 547	A1	Unilever PLC	04-22-1992		
		EP	0 788 790	A2	Jagotec AG	02-06-1996		
		EP	0 861 659	A1	University of Kentucky Research Foundation	02-21-1992		
		EP	0 864 324	B1	BASF Aktiengesellschaft (English abstract attached)	03-12-1997		
		EP	0 950 402	B1	McNeil-PPC, Inc.	02-22-1999		
		EP	1 077 065	A1	Chugai Seiyaku Kabushiki Kaisha	02-21-2001		
		GB	994 742		The Wellcome Foundation Limited	05-04-1961		
		GB	888 038		The Wander Company	01-24-1962		
		GB	936 386		The Wellcome Foundation Limited	09-11-1963		
		GB	1 144 915		Armour Pharmaceutical Company	03-12-1969		
		GB	1 372 040		Boehringer Ingelheim	10-30-1974		
		GB	2 197 778	A	Katjes Fassin GmbH & Co. KG	06-02-1988		
		GB	2 284 760	A	Euroceltique S.A.	06-21-1995		
		WO	94/06416	A1	Ubaldo Conte et al.	03-31-1994		
		WO	95/02396	A1	Smithkline Beecham Corporation	01-26-1995		
		WO	95/15156	A1	LTS Lohmann Therapie-Systeme GmbH & Co. KG	06-08-1995		
		WO	97/06695	A1	The Procter & Gamble Company	02-27-1997		
		WO	97/15293	A2	BASF Ak-Tiengelsellschaft	05-01-1997		
		WO	98/20870	A1	Pozen Inc.	05-22-1998		
		WO	99/51209	A1	Impax Pharmaceuticals, Inc.	10-14-1999		
		WO	99/56730	A1	Alza Corporation	11-11-1999		
		WO	00/18447	A2	Impax Pharmaceuticals, Inc.	04-06-2000		

Examiner Signature		Date Considered	
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 3

Application Number	09/966,497
Filing Date	September 28, 2001
First Named Inventor	Harry S. Sowden
Group Art Unit	1732
Examiner Name	Angela Y. Ortiz
Attorney Docket Number	MCP-294

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>2</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		WO	00/25755	A1	Fuisz Technologies Ltd.	05-11-2000		

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		LACHMAN, Leon et al., "Chapter II - Tablets", The Theory and Practice of Industrial Pharmacy, (1986); pp. 293-345	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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